Office of Management Systems

Division of Management Services and Policy. Division of Planning and Financial Management.

Division of Information Resources Management.

Division of Administrative Services.

Office of Scientific Analysis and Support

Division of Mathematics.

Division of General Scientific Support. Division of Market Studies.

CENTER FOR VETERINARY MEDICINE 16

Office of the Center Director

Office of Management

Division of Program and Information Systems.

Division of Program Communications and Administrative Management.

Office of Surveillance and Compliance

Division of Compliance.

Division of Animal Feeds.

Division of Surveillance.

Division of Voluntary Compliance and Hearings Development.

Office of New Animal Drug Evaluation

Division of Chemistry.

Division of Therapeutic Drugs for Food Animals

Division of Therapeutic Drugs for Non-Food Animals.

Division of Toxicology and Environmental Sciences.

Office of Science

Division of Residue Chemistry. Division of Animal Research.

[60 FR 16568, Mar. 31, 1995, as amended at 61 FR 8472, Mar. 5, 1996]

§5.105 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Associate General Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human

Services, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981, as amended at 56 FR 8709, Mar. 1, 1991]

§5.110 FDA Public Information Offices.

- (a) Dockets Management Branch (HFA-09305). The Dockets Management Branch Public Room is located in rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Telephone: 301-443-1753.
- (b) Freedom of Information Staff (HFI-0935). The Freedom of Information Public Room is located in Room 12A-30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-6310.
- (c) Press Relations Staff (HFI-0940). Press Offices are located in Room 15-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-3285; and in Room 3807, FB-8, 200 C Street SW., Washington, DC 20204. Telephone: 202-245-1144.

[46 FR 8455, Jan. 27, 1981, as amended at 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994]

§5.115 Field structure.

NORTHEAST REGION

Regional Field Office: 830 Third Ave., Brooklyn, NY 11232.

Northeast Regional Laboratory: 850 Third Ave., Brooklyn , NY 11232.

New York District Office: 850 Third Ave., Brooklyn, NY 11232.

Boston District Office: One Montvale Ave., Stoneham, MA 02180.

Buffalo District Office: 599 Delaware Ave., Buffalo. NY 14202.

MID-ATLANTIC REGION

Regional Field Office: 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106.

Philadelphia District Office: 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106.

Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201.

Cincinnati District Office: 1141 Central Pkwy., Cincinnati, OH 45202–1097.

Newark District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d floor, Parsippany, NJ 07054.

¹⁶ Mailing address: 7500 Standish Pl., Rockville. MD 20855.

§ 7.1

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.

New Orleans District Office: 4296 Elysian Fields Ave., New Orleans, LA 70122.

Orlando District Office: 7200 Lake Ellenor Dr., suite 120, Orlando, FL 32809.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

MIDWEST REGION

Regional Field Office: 20 North Michigan Ave., rm. 510, Chicago, IL 60602.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401.

SOUTHWEST REGION

Regional Field Office: 3032 Bryan St., Dallas, TX 75204

Dallas District Office: 3032 Bryan St., Dallas,

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225-0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214-3340.

St. Louis Branch: 808 North Collins Alley, St. Louis, MO 63102.

PACIFIC REGION

Regional Field Office: Federal Office Bldg., rm. 568, 50 U.N. Plaza, San Francisco, CA 94102

San Francisco District Office: Federal Office Bldg., rm. 526, 50 U.N. Plaza, San Francisco,

Los Angeles District Office: 1521 West Pico Blvd., Los Angeles, CA 90015-2486.

Seattle District Office: 22201 23d Dr. SE., Bothell, WA 98021-4421.

[60 FR 16570, Mar. 31, 1995]

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Sec.

7.1 Scope.

7.3 Definitions.

7.12 Guaranty.

7.13 Suggested forms of guaranty.

Subpart B—[Reserved]

Subpart C-Recalls (Including Product Corrections)—Guidelines on Policy, Procedures, and Industry Responsibil-

7.40 Recall policy.7.41 Health hazard evaluation and recall classification.

7.42 Recall strategy.7.45 Food and Drug Administration-requested recall.

7.46 Firm-initiated recall.

7.49 Recall communications.

Public notification of recall.

Recall status reports. Termination of a recall.

General industry guidance.

Subpart D—[Reserved]

Subpart E—Criminal Violations

7.84 Opportunity for presentation of views before report of criminal violation.

7.85 Conduct of a presentation of views before report of criminal violation.

7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

AUTHORITY: Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393); secs. 301, 351, 354-360F, 361 of the Public Health Service Act (42 U.S.C. 241, 262, 263b-263n, 264).

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978]